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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,117	12/30/2003	David M. Gravett	110129.434	3276

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	**PAPER NUMBER**
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/749,117	GRAVETT ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,10,13,14,17-21,75,84-99,102 and 105-112* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,10,13-14,17-21,75,84-99,102 and 105-112* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment to the claims filed 11/28/2006 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6,10,75, 84-99,102 and 105-112 are rejected under 35 U.S.C. 102(b) as being anticipated by Wallace et al. (US 6,312,725). This new rejection was necessitated by amendment.

Wallace teaches rapid gelling (<1 min) biocompatible polymer compositions that can be used for *in vivo* administration that are comprised of two components, the first is a nucleophilic PAO containing 4-12 sulfhydryl nucleophilic groups and the second is an electrophilic PAO which can contain a mixture of between 4-12 succinimidyl and maleimidyl electrophilic groups, the composition can further contain optional materials such as drugs, antibiotics and methylated collagen. See abstr, col 1 lin 66-col 2 lin 60, col 4 lin 8-67, col 5 lin 9-col 6 lin 8, col 8 lin 9-23, col 10 lin 55-col 11 lin 2, examples and claims. Regarding the new limitation in claims 1,89-93 that the biocompatible gel-forming drug delivering composition further comprises a secondary carrier, the secondary carrier incorporating the drug, the examiner used the broadest reasonable interpretation of "secondary carrier" to mean a pharmaceutically acceptable solvent, suspending agent or vehicle for delivering a bioactive agent and the examiner defined

incorporated as to mix (something in) as an ingredient; or to blend. Wallace discloses several optional composition constituents which may be blended in the composition, the constituents could become covalently incorporated within the matrix itself by crosslinking or physically and/or ionically associated with the matrix, thus it essentially becomes part of the matrix itself. The drugs used in Wallace were said to be released through diffusion controlled process or may be covalently bound to the components such that it will be released as the resulting hydrogel degrades. Wallace meets the new limitation that the composition further comprises a secondary carrier which incorporates the drug, because the drug and consitutent are blended with the two PAO components. See col 7 lin 61-col 8 lin 38 and col 10 lin 55-63. Wallace also teaches that the nucleophilic polymer can be contained in an alkaline buffer solution of sodium phosphate/carbonate within the pH range specified by applicants and the electrophilic polymer can be contained in an acidic buffer solution. See col 9 lin 12-45 and examples. Each component of the composition is administered separately to the tissue site or both together, then within a short time after being mixed together at the site of administration the composition forms a gel, this statement in the Wallace patent meets the limitations in claim 89 that the first and second component are administered sequentially or subsequently, the drug is contained within the PAO gel. See col 3 lin 25-32 and examples.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6,10,13-14,17-21,75, 84-99,102 and 105-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al. (US 6,312,725) in view of Loomis (US 5,854,382). This new rejection was necessitated by amendment.

Wallace is disclosed above. Wallace while disclosing that the gels can comprise drugs the patent is silent on specific drugs such as paclitaxel. As disclosed above Wallace would obviously meet the new limitation that the biocompatible gel-forming drug-delivering composition further comprises a secondary carrier, the secondary carrier incorporating the drug.

Loomis is used to primarily show that the use of paclitaxel in biocompatible crosslinked PAO gels was well known in the art at the time of invention. See abstr, col 5 lin 36-51, col 7 lin 10-16.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Wallace discloses all that is claimed within applicants current application but is silent on the use of the exact drug paclitaxel while the Loomis patent discloses that it was well known in the art to use paclitaxel in biocompatible crosslinked PAO gels. The motivation to combine the above documents would be the formation of a rapid gelling biocompatible polymer composition comprising anti-tumor agents such as paclitaxel. The advantage of such a composition would be a diffusion-controlled release of paclitaxel for tissue treating applications requiring rapid adhesion. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 572-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER